UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No.1456 Master File No. 01-CV-12257-PBS Subcategory No. 06-CV-11337-PBS Judge Patti B. Saris Magistrate Judge Marianne B. Bowler
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Boehringer Ingelheim Corporation, et al.*, Civil Action No. 07-10248-PBS	

THE ROXANE DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION UNDER THE PUBLIC DISCLOSURE BAR OF THE FALSE CLAIMS ACT

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TABLE OF CONTENTS

Page

INTRODUCTION 1

I. VAC'S CLAIMS ARE BARRED BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED ALLEGATIONS, AND VAC IS NOT AN ORIGINAL SOURCE. 2

A. The Public Disclosure Inquiry Requires A Drug-By-Drug Analysis And Includes Disclosures That Predate The Addition Of New Drugs In Amended Complaints.....2

B. The Public Disclosures Reveal The Essential Elements Of VAC's Allegations. 5

1. The Public Disclosures Specifically Revealed The "Z"-Fraud Allegations: The Alleged "Scheme" and "How it Worked."....6

2. The Public Disclosures Also Revealed The "Y"-Allegations For Ipratropium: "Mega-Spreads" And The Link To Roxane. 10

3. Allegations Of Fraud For The Additional Drugs Were Publicly Disclosed By February 2005, The Critical "Public Disclosure" Date. 13

C. VAC Is Not An "Original Source" Because It Lacks Direct Knowledge.....14

II. THE GOVERNMENT'S COMPLAINT CANNOT RELATE BACK TO VAC'S PRE-INTERVENTION COMPLAINTS BECAUSE EACH OF THOSE PLEADINGS WAS JURISDICTIONALLY DEFECTIVE. 16

A. The New FERA Relation-Back Provision Is Inapposite.....17

CONCLUSION.....19

TABLE OF AUTHORITIES

Page(s)

Cases

Bannon v. Edgewater Med. Ctr.,
406 F. Supp. 2d 907 (N.D. Ill. 2005) 3, 16

Campbell v. Redding Med. Ctr.,
421 F.3d 817 (9th Cir. 2005) 18

Connectu LLC v. Zuckerberg,
522 F.3d 82 (1st Cir. 2008) 17

Fuller v. Volk,
351 F.2d 323 (3d Cir. 1965) 17

In re Pharm. Indus. AWP Litig.,
01-12257-PBS, 2007 WL 4287572 (D. Mass. Dec. 6, 2007) 4

In re Pharm. Indus. AWP Litig.,
491 F. Supp. 2d 20 (D. Mass. 2007) 4

Rockwell Int'l Corp. v. United States,
549 U.S. 457 (2007) ..... passim

United States ex rel. Atkinson v. Pa. Shipbuilding Co.,
255 F. Supp. 2d 351 (E.D. Pa. 2002) 2, 3, 14

United States ex rel. Atkinson v. Pa. Shipbuilding Co.,
473 F.3d 506 (3d Cir. 2007) 15

United States ex rel. Barth v. Ridgedale Elec., Inc.,
44 F.3d 699 (1995) 15, 16

United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.,
06-4091, 2009 WL 3353314 (E.D. La. Oct. 19, 2009) 12

United States ex rel. Cosens v. Yale-New Haven Hosp.,
233 F. Supp. 2d 319 (D. Conn. 2002) 17

United States ex rel. Dingle v. BioPort Corp.,
270 F. Supp. 2d 968 (W.D. Mich. 2003) 9

United States ex rel. Hafter v. Spectrum Emergency Care, Inc.,
190 F.3d 1156 (10th Cir. 1999) 14

United States ex rel. Haight v. Catholic Healthcare W.,
445 F.3d 1147 (9th Cir. 2006) 6

United States ex rel. Kennedy v. Aventis Pharms.,
512 F. Supp. 2d 1158 (N.D. Ill. 2007) 11

United States ex rel. Kreindler & Kreindler v. United Tech. Corp.,
985 F.2d 1148 (2d Cir. 1993) 16

United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.,
4:05-CV-00899 GTE, 2007 WL 2904111 (E.D. Ark. Sept. 28, 2007) 3

United States ex rel. O'Keeffe v. Sverdup Corp.,
131 F. Supp. 2d 87 (D. Mass. 2001) 14, 16

United States ex rel. Poteet v. Lenke,
604 F. Supp. 2d 313 (D. Mass. 2009) 18

United States ex rel. Poteet v. Medtronic, Inc.,
552 F.3d 503 (6th Cir. 2009) 18

United States ex rel. Radcliffe v. Purdue Pharma, L.P.,
582 F. Supp. 2d 766 (W.D. Va. 2008) 6, 11

United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.,
384 F.3d 168 (5th Cir. 2004) 6

United States ex rel. Sanders v. Allison Engine Co., Inc.,
1:95-cv-970, 1:99-cv-923, 2009 WL 3626773 (S.D. Oh. Oct. 27, 2009) 19

United States ex rel. Smith v. Yale Univ.,
415 F. Supp. 2d 58 (D. Conn. 2006) 15

United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.,
944 F.2d 1149 (3d Cir. 1991) 16

United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC,
08-CV-10852-PBS, 2009 WL 3171798 (D. Mass. Oct. 2, 2009) ..... passim

United States ex rel. West v. Ortho-McNeil Pharm., Inc.,
538 F. Supp. 2d 367 (D. Mass. 2008) 12, 14

United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.,
528 F.3d 292 (4th Cir. 2008) 2, 5

United States Steel Corp. v. EPA,
614 F.2d 843 (3d Cir. 1979) 17

United States v. Aguillon,
628 F. Supp. 2d 542 (D. Del. 2009) 18

United States v. Alcan Elec. & Eng'g,
197 F.3d 1014 (9th Cir. 1999) 12, 14

Statutes

31 U.S.C. § 3730(b)(5) 18

31 U.S.C. § 3730(e)(4) 2, 3, 4, 18

31 U.S.C. § 3730(e)(4)(A) 2

FERA, Pub. L. No. 111-21,
§4(f)(2), 123 Stat. 1621 (2009) 17

INTRODUCTION

Ven-A-Care ("VAC") misstates the significance of this Court's opinion in *United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 08-CV-10852-PBS, 2009 WL 3171798 (D. Mass. Oct. 2, 2009), which was based on a different evidentiary record involving different drugs, time periods, and defendants. Not only does VAC overestimate the importance of *Actavis* to the issues presented in this Motion, but it also miscalculates the result that *Actavis* yields when applied to these facts. With the benefit of discovery, Roxane has identified numerous disclosures that effectively revealed all of the crucial information the Court found lacking in *Actavis*. Public disclosures of potential "fraud" and the existence of "mega-spreads" *are* present here, particularly in the case of ipratropium bromide ("Ipratropium"). In fact, by April 2002, when VAC asserted its belated AWP claims against Roxane, public discussion was so pervasive, including in extensive Congressional hearings, that this Court held that "a perfect storm of information" regarding mega-spreads had reached even unsophisticated third-party payors. Thus, VAC's contention that its allegations, extending all the way to 2005, circumvent the public disclosure bar is contrary to both the factual record and black-letter FCA law.

Moreover, despite VAC's purported efforts to "expose" spreads that were self-evident and readily available, VAC is not an original source. As opposed to being "marked by the absence of an intervening agency," VAC's knowledge can only be described as derivative. Indeed, VAC does not even attempt to refute that it obtained ***all*** the core information on Roxane prices second-hand from third-party sources. Thus, VAC is, at best, twice removed from the direct knowledge required of an original source.

Accordingly, this Court lacks jurisdiction over this action unless and until VAC's claims are dismissed. Moreover, the Government's claims cannot relate back to VAC's jurisdictionally defective complaints.

I. VAC'S CLAIMS ARE BARRED BECAUSE THEY ARE BASED ON PUBLICLY DISCLOSED ALLEGATIONS, AND VAC IS NOT AN ORIGINAL SOURCE.

A. The Public Disclosure Inquiry Requires A Drug-By-Drug Analysis And Includes Disclosures That Predate The Addition Of New Drugs In Amended Complaints.

In attempt to neutralize the public disclosures identified by Roxane, VAC contends that the temporal scope of the public disclosure inquiry extends no further than April 10, 2000, the date this action was initially filed. (VAC's Opp. at 22-23, 46) VAC, however, ignores that the initial complaint only raised allegations as to one drug (Ipratropium), and VAC added numerous new drugs and new allegations over the following five years. According to VAC, public disclosures occurring after 2000 are untimely and irrelevant because VAC's amended complaints purportedly did not constitute "new or different action[s]." (*Id*. at 46, 23)

VAC's theory is contradicted by the sole authority that it relies on. *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007) does not stand for the proposition that only "new or different actions" trigger the public disclosure analysis. Rather, *Rockwell* establishes the opposite: the focus of the jurisdictional inquiry under 31 U.S.C. § 3730(e)(4) is not the "action" as a whole, but each discrete claim asserted in the action. *Rockwell*, 549 U.S. at 474, 476. Consistent with this principle, courts have explicitly rejected the "action-based" approach that VAC proposes, in favor of a "claim-based" analysis. *United States ex rel. Atkinson v. Pa. Shipbuilding Co*., 255 F. Supp. 2d 351, 369 n.18 (E.D. Pa. 2002). Accordingly, the public disclosure inquiry here must "proceed on a claim-by-claim basis, individually addressing 'each [of VAC's] reasonably discrete claim[s] of fraud' . . . ." *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist*., 528 F.3d 292, 309 (4th Cir. 2008).

VAC also ignores the plain language of 31 U.S.C. § 3730(e)(4)(A), which bars actions based on the public disclosure of "allegations," not of "allegations in the initial complaint," or of

"allegations 'that constitute a new or different action.'" *Rockwell*, 549 U.S. at 473 ("Absent some limitation of § 3730(e)(4)'s requirement to the relator's *initial* complaint, we will not infer one."). Therefore, the proper inquiry is not whether the public disclosure antedated the inception of the action, but, rather, whether the public disclosure of a given allegation predated the appearance of that allegation in the relator's complaints. *Atkinson*, 255 F. Supp. 2d at 368 n.15; *Bannon v. Edgewater Med. Ctr.*, 406 F. Supp. 2d 907, 924 (N.D. Ill. 2005) ("There is no principled difference between a *complaint* based upon information contained in public disclosures . . . and an *amended complaint* that is based upon . . . that information."). Otherwise, the relator could readily circumvent § 3730(e)(4) by asserting claims that have *not* been publicly disclosed, only to add claims that *have* been publicly disclosed in amended pleadings. *See Rockwell*, 549 U.S. at 473; *United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr.*, 4:05-CV-00899 GTE, 2007 WL 2904111, *8-9 (E.D. Ark. Sept. 28, 2007). The Supreme Court, "along with every court to have addressed the question, [has] conclude[ed] that § 3730(e)(4) does not permit such claim smuggling." *See Rockwell*, 549 U.S. at 476.

Claim smuggling is precisely what VAC seeks to do here. The array of claims presently at issue were asserted by VAC over the course of at least five years in three different pleadings.[1] For instance, while VAC alleged WAC-fraud for Ipratropium in its 2000 Complaint, it did not

[1] The relevant pleadings for the purpose of this Reply Brief are VAC's initial complaint, filed on April 10, 2000 ("2000 Complaint"); VAC's Second Amended Complaint, filed on February 1, 2002 ("2002 Complaint"); VAC's Third Amended Complaint, filed on February 15, 2005 ("2005 Complaint"); and the Government's December 2, 2008 complaint (the "Complaint"), the operative complaint in this action, which VAC adopted in its entirety. In the interim between filing its 2000 and 2002 Complaints, VAC filed a First Amended Complaint, without any substantive modifications or additions.

allege AWP-fraud for Ipratropium until its 2002 Complaint.[2] For the eight other drugs at issue (the "Additional Drugs"), VAC did not allege *any* fraud until it filed its 2005 Complaint. By VAC's logic, only claims of WAC-fraud for Ipratropium are subject to the public disclosure bar-the rest are somehow insulated from jurisdictional scrutiny. Not only is this interpretation contrary to FCA precedent, but it would defeat the very purpose of § 3730(e)(4). Indeed, by the time VAC alleged AWP-fraud for Ipratropium in 2002, and well before adding the Additional Drugs in 2005, there was "a perfect storm of information" from which any parasitic relator could have copied such claims. *In re Pharm. Indus. AWP Litig*., 491 F. Supp. 2d 20, 41 (D. Mass. 2007).

VAC's interpretation is also at odds with this Court's prior holdings. This Court has already determined that claims involving the Additional Drugs are not "sufficiently related" to the claims involving Ipratropium for relation-back purposes. *In re Pharm. Indus. AWP Litig*., 01-12257-PBS, 2007 WL 4287572, *3 (D. Mass. Dec. 6, 2007). In reaching this conclusion, the Court specifically rejected the argument-raised then by the Government, now by VAC-that a sufficient relationship existed because all drugs were part of "one 'broad scheme.'" *Compare id*. (arguing that "the new drugs are part of the same 'broad scheme of price manipulation' . . . .") *with* VAC's Opp. at 46 (arguing that VAC "merely added drugs that were part of the [same] fraud scheme alleged in its original action . . . ."). Similarly, allegations regarding Ipratropium in VAC's 2000 Complaint did not cut short the public disclosure inquiry for allegations regarding the Additional Drugs, which VAC did not raise until five years later in the 2005 Complaint.

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[2] VAC does not, and cannot, cite to any allegation of AWP-inflation by Roxane in its 2000 Complaint, in direct contrast to the 2002 Complaint. Thus, VAC concedes that the allegations of AWP-inflation for Ipratropium were raised in, and thus need not have been disclosed any earlier than, the 2002 Complaint.

In sum, as the foregoing principles dictate, the critical dates for purpose of the public disclosure analysis are the dates on which VAC first raised the allegations on which each of its "reasonably discrete claim[s] of fraud is based," *Wilson*, 528 F.3d at 309:

Public Disclosure Date	**Allegations on which VAC's Core Claims of Fraud Are Based**
April 10, 2000	VAC alleges that Roxane inflated the WACs for Ipratropium. (Roxane Dkt. No. 2, Ex. 1 ¶¶ 86-88)[3]
February 1, 2002	VAC alleges that Roxane inflated the AWPs for Ipratropium. (Roxane Dkt. No. 2, Ex. 3 ¶¶ 173-78)
February 15, 2005	VAC alleges that Roxane inflated and marketed the spread on the WACs and AWPs for all nine drugs at issue. (Roxane Dkt. No. 2, Ex. 4 ¶¶ 131, 132.b)

B. The Public Disclosures Reveal The Essential Elements Of VAC's Allegations.

Contrary to VAC's assertions, the "pertinent facts and allegations" in this action are not "parallel" to those presented in *Actavis*. (VAC's Opp. at 13) Here, an evidentiary record developed in extensive discovery demonstrates the public disclosure of the purported fraud and the existence of mega-spreads, particularly with respect to Ipratropium.

In *Actavis*, the Court held that the government reports alone did not constitute a public disclosure because they do not convey the "Z"-fraud allegations-that "AWPs are being used as part of a scheme to defraud the government" or "any indication of how the scheme works . . . ." *Actavis*, 2009 WL 3171798, at *3. Nor did they fully disclose the "Y"-allegations (*i.e.*, the actual true set of facts) because they "did not point to the existence of the mega-spreads at the heart of this case," *id*. at *4, and the "Defendants and the drugs at issue [were] not readily identifiable" from the reports, *id*. at *5. Roxane respectfully suggests that the Court's

[3] Citations to the "Roxane Docket" refer to the docket for Case No. 07-10248-MEL, while citations to the "Docket" refer to Case No. 06-11337-PBS.

conclusions in *Actavis* are erroneous, but in any event, the public disclosures specific to Roxane and its drugs are, as a matter of fact, sufficient to trigger the original source inquiry.

As an initial matter, VAC improperly considers the public disclosures *separately*, rather than viewing them *as a whole*, which is what the law requires. *United States ex rel. Haight v. Catholic Healthcare W.*, 445 F.3d 1147, 1151 n.1 (9th Cir. 2006); *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004). When considered as a whole, both the "X" and "Y," as well as the "Z" are revealed. As discussed below, in addition to the "essential background information" provided in the government reports, *Actavis*, 2009 WL 3171798, at *3, there are several key public disclosures here, that furnish the elements of information found missing in *Actavis*.

1. *The Public Disclosures Specifically Revealed The "Z"-Fraud Allegations: The Alleged "Scheme" and "How it Worked."*

Allegations of pricing fraud by drug manufacturers in general, and specifically with regard to Ipratropium, were publicly disclosed before this action was filed in April 2000, and certainly before February 2002, when VAC first alleged AWP-inflation. Indeed, by 2000, the news media had resoundingly reported purposeful AWP-inflation, using words and phrases that unmistakably imputed the type of "fraud" that VAC now purports to attribute to Roxane.[4] In statements to the public, AWP was variously described as follows:

[4] VAC's attempt to distinguish the "industry trade publications" cited by Roxane from "traditional 'news media'" is unavailing. (VAC's Opp. at 17) "The term 'news media' includes scholarly, scientific, and technical periodicals, ***including trade journals***, because, like newspapers, these sources disseminate information to the public in a periodic manner." *United States ex rel. Radcliffe v. Purdue Pharma*, L.P., 582 F. Supp. 2d 766, 770 (W.D. Va. 2008) (emphasis added).

YEAR	STATEMENT
1987:	— "The (Average Wholesale Price) is ***a joke*** . . . . It has largely become ***a farce*** because many companies have abused it and continue to abuse it." (Tab 73, Roxane SOF, 7/5/87 *Lexington Herald-Leader* at 3 (emphasis added))[5] — "The Average Wholesale Price 'just doesn't mean anything. It has no connection to what pharmacists really purchase the drug for . . . ." (*Id*.)
1989:	— "The situation with [AWPs for] generic drugs is ***a sham*** . . . . It's ***a joke*** . . . ." (Tab 74, Roxane SOF, 2/12/89 *Phila. Inquirer* at 3 (emphasis added)) — "Let's face it . . . AWP is ***a joke*** . . . It is simply ***a figure of manufacturers' imaginations*** . . . . Once the AWP is in the government's hands . . . [i]t will be scrutinized and uncovered for what it is-***a sham***." (Tab 78, Roxane SOF, 5/1/89 *Drug Store News* at 2 (emphasis added))
1990:	— "Unfortunately, AWP has become ***an exploited figure*** that is often ***picked out of thin air by pharmaceutical manufacturers*** who know that as long as third-party programs continue to use AWP as a base for reimbursement, ***the higher the number the better their chances are of getting their product dispensed***." (Tab 86, Roxane SOF, 6/11/90 *Drug Store News* at 1 (emphasis added))
1996:	— "AWP really means '***Ain't What's Paid***[.]'" (Tab 95, Roxane SOF, 6/10/96 *Barron's* at 15 (emphasis added); Tab 89, Roxane SOF, Aug. 1997 OIG Report at 1-2, *citing Barron's*) — "The problem is, the [AWP] is too often ***a fantasy number*** . . . . The AWP figures reported in such sources as Drug Topics Red Book, American Druggist Blue Book, or Medispan are simply not reflective of what the reimbursed price should be." (Tab 92, Roxane SOF, 2/27/96 Statement of Rep. P. Stark in the H.R. at 1 (emphasis added))

5 This Reply Brief cites to The Roxane Defendants' Corrected Local Rule 56.1 Statement of Undisputed Material Facts in Support of Their Motion for Summary Judgment ("Roxane SOF"), to the extent evidence cited in the Roxane SOF also supports the arguments in this Reply. (Dkt. No. 261)

YEAR	STATEMENT
1997:	— "The problem with AWP is that it is ***essentially an artificial price open to manipulation***. If the discount off AWP is increased by third party payers such as Medicaid, the price can eventually be adjusted over time to maintain the profit margin." (Ex. P, Feb. 1997 OIG Report at App. 4, p. 1 (emphasis added)) — "[P]ublished ***AWPs*** . . . ***bear little or no resemblance to actual wholesale prices*** that are available to the physician and supplier communities that bill for these drugs." (Tab 97, Roxane SOF, Dec. 1997 OIG Report at ii (emphasis added); Tab 73, Roxane SOF, 7/5/89 *Lexington Herald-Leader* at 1, 3)
1999:	— "Unfortunately, the ***AWP is a joke on the taxpayer*** . . . . It really stands for '***Ain't What's Paid***.' The real price to doctors and others is much, much lower, yet Medicare blindly continues to pay this ***fictitious 'sticker price'*** . . . . Medicare continue[s] to overpay at least $1 billion a year because of ***the phony Average Wholesale Price system***." (Tab 104, Roxane SOF, 9/2/99 Stark Press Release at 1 (emphasis added))

Moreover, four years before VAC filed its 2000 Complaint, Representative Pete Stark-who VAC touts as "the most influential member of Congress . . . in the healthcare arena" (VAC Opp. at 1) -unequivocally and publicly accused drug manufacturers of manipulating AWP to defraud the government. Specifically, Mr. Stark alerted Congress that: "Medicare-and private payors- are being ***defrauded*** by pharmaceutical companies and pharmaceutical sales organizations because our basis of paying for these drugs-the average wholesale price or AWP-is grossly overstating the true price of these drugs to health care providers." (Tab 92, Roxane SOF, 2/27/96 Statement of Rep. P. Stark in the H.R. (emphasis added)) Representative Stark went on, and further urged Congress to take action to "stop[] the ***fraud*** and waste that is plaguing this part of the nation's health care system." (*Id*. (emphasis added)) Thus, in 1996, the "most influential" Congressional member on healthcare policy explicitly and publicly disclosed precisely the fraud allegations that VAC belatedly asserted against Roxane years later, and that

go squarely to the Court's concerns in *Actavis*. *Compare id. with Actavis*, 2009 WL 3171798, at *3 (holding that the government reports themselves were not public disclosures because they did not suggest that "AWPs are being used as part of a scheme to defraud the government"); *see also United States ex rel. Dingle v. BioPort Corp*., 270 F. Supp. 2d 968, 975 (W.D. Mich. 2003) (statements made during congressional hearings constitute public disclosures).

In addition, before this action commenced, "indications of *how* the scheme works" had also emerged publicly. On many occasions, news media reporters announced to the general public that drug manufacturers were creating excessive "spreads" by raising AWPs without raising wholesale prices (Tab 73, Roxane SOF, 7/5/89 *Lexington Herald-Leader* at 7), and/or by reducing wholesale prices without lowering AWP (Tab 95, Roxane SOF, 6/10/96 *Barron's* at 16 ("generic AWPs stay at their lofty perches, or even rise, as competition forces a drug's true wholesale price into the abyss"); Ex. P, Feb. 1997 OIG Report at App. 4, p. 1). Information regarding *who* created the "spreads" was also specifically revealed: "[O]f course, the AWP is being manipulated by many pharmaceutical manufacturers." (Tab 78, Roxane SOF, 5/1/89 *Drug Store News* at 2) So, too, were explanations regarding *why*: Pharmacists "will use or substitute the product with the best AWP to receive a higher rate of reimbursement" (*id*.); "the higher [the AWP,] the better [the manufacturer's] chances are of getting [its] product dispensed" (Tab 86, Roxane SOF, 6/11/90 *Drug Store News* at 1); and, though drug manufacturers do not "directly profit" from the "lofty AWPs," they "might . . . gain market share [from them] and higher sales from their customer's over-utilization" (Tab 95, Roxane SOF, 6/10/1996 *Barron's* at 16).

Nor was the Government ignorant of "how the scheme worked." In a May 1998 report, the OIG succinctly summarized the gist of the alleged "scheme":

> Because AWP is usually used as a basis for reimbursement at the pharmacy level, ***manufacturers can use it as a marketing tool to gain market share***. For

> example, by increasing AWP, manufacturers can give pharmacies more Medicaid reimbursement . . . . (Tab 102, Roxane SOF, May 1998 OIG Report at 5 (emphasis added))

The notion that pharmaceutical manufacturers were using AWPs and the resulting spreads purportedly to gain market share is the *heart* of VAC's AWP-fraud allegations against Roxane. Here, the OIG, which this Court described as the "pit bull" responsible for informing HCFA (and others) of AWP issues throughout the 1990s, explicitly and publicly revealed these same fundamental allegations. And the OIG did so at least two years before VAC filed its initial complaint against Roxane.

2. *The Public Disclosures Also Revealed The "Y"-Allegations For Ipratropium: "Mega-Spreads" And The Link To Roxane.*

Amidst the foregoing volley of disclosures, allegations of mega-spreads for Ipratropium, specifically linking the drug to the "Z"-fraud "scheme," also reached the public. In the mid-1990's, the OIG, Representative Stark, and the GAO embarked on an investigation of nebulizer products that lead directly to Ipratropium. In 1996, the OIG concluded that HCFA had overpaid for nebulizer products, like Ipratropium, by millions of dollars. (Tab 127, Roxane SOF, Feb. 1996 OIG Report at 6) Then in 1998, the OIG issued a report scrutinizing the acquisition costs of Ipratropium in particular, and disclosing average spreads of 155%. (Tab 129, Roxane SOF, Nov. 1998 OIG Report at 7, 8, App. B-1)

In direct reaction to the 1998 OIG Report, Representative Stark issued a press release announcing the very Ipratropium "mega spreads" that VAC claims were concealed until it filed its 2000 Complaint. Specifically, Representative Stark announced that from 1996 to 2000, "the cost of Ipratropium Bromide to druggists and doctors ha[d] dropped by 50%." (Tab 130, Roxane

SOF, 9/1/99 Stark Press Release at 1)[6] Yet "the amount per unit that Medicare pays for this drug ha[d] stayed the same." (*Id.*) The press release compared and contrasted, to the decimal, the per unit Medicare reimbursement with the average per unit cost to providers, illustrating spreads of: 15% in 1996; 63% in 1997; 96% in 1998; and 108% in 1999. (*Id.*)[7] One year later, Representative Stark publicized these same allegations regarding mega-spreads for Iptratropium, this time in the House of Representatives. (Ex. Q, 9/19/00 Statement of Rep. P. Stark in the H.R.) Similarly, in January 2001 (a year before VAC alleged any AWP-fraud), Representative Stark specifically identified Ipratropium "spreads" as evidence that drug companies were "manipulate[ing]" AWPs to increase utilization and profits at the expense of taxpayers. (Ex. R, 1/30/01 Statement of Rep. P. Stark in the H.R.)

Plainly, these public statements disclosed particularized "Y" and "Z" allegations of mega-spreads and fraud for Ipratropium, before VAC filed its 2000 Complaint, and *certainly* before VAC first alleged AWP-fraud in its 2002 Complaint.

Neither can VAC refute that its allegations were publicly disclosed in the 2001 GAO Report. After a lengthy study of reported prices and provider invoices, the GAO concluded that the average discount for Ipratropium was 78%, equating to a spread of 355%. (Tab 131, Roxane SOF, Sept. 2001 GAO Report at 4, 18) In VAC's view, this report is not disabling because it

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6 VAC suggests that the term "news media" does not encompass press releases. However, courts have rejected this argument, holding that press releases appearing on the internet are a type of news media fully capable of generating a public disclosure. *Radcliffe*, 582 F. Supp. 2d at 766; *United States ex rel. Kennedy v. Aventis Pharms.*, 512 F. Supp. 2d 1158, 1164 (N.D. Ill. 2007). This press release, which was posted on Representative Stark's official website, constitutes a public disclosure via the news media.

7 Whether VAC provided the information on which this or other public disclosures were based is immaterial. Indeed, as the Supreme Court has noted, "[i]t is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation . . . ." *Rockwell*, 549 U.S. at 471. And while such fact may contribute to establishing knowledge "independent" of the public disclosure, it sheds no light on whether VAC has "direct" knowledge of the information on which its allegations are based.

does not predate the filing of this action. (VAC's Opp., Ex. B at 12, No. 32) However, as indicated above, the public disclosure inquiry is a claim-by-claim analysis, the scope of which is limited in time, not by the date an FCA action is filed, but by the date on which a particular claim was raised. *See* discussion *supra* at §I.A. Because VAC did not assert any AWP-related claims against Roxane until 2002, the 2001 GAO report falls squarely within the relevant timeframe.

That Roxane was not specifically named in these disclosures is of no consequence because its identity was readily identifiable. *See United States ex rel. West v. Ortho-McNeil Pharm., Inc*., 538 F. Supp. 2d 367, 383 n.10 (D. Mass. 2008). Nor does it matter whether the Government *actually* knew which or how many companies sold Ipratropium.[8] *United States v. Alcan Elec. & Eng'g*, 197 F.3d 1014, 1019 (9th Cir. 1999) (holding that a public disclosure occurred because the government had "ready access" to documents confirming the identity of the alleged wrongdoers). What matters is that the public disclosures provided information sufficient to "set the government squarely on the trail of fraud," as is the case here. *Ortho-McNeil*, 538 F. Supp. 2d at 383 n.10. Indeed, in 1998, at the time of the initial OIG report on Ipratropium, Roxane was *one of two* companies selling Ipratropium. And at no point were there ever more than a handful of manufacturers. Given such a "narrow class of suspected wrongdoers," the Government could have easily traced the allegations of Ipratropium-fraud and mega-spreads to Roxane. *Actavis*, 2009 WL 3171798, at *4, *citing Alcan*, 197 F.3d at 1019; *United States ex rel. Branch Consultants, L.L.C. v. Allstate Ins. Co.*, 06-4091, 2009 WL 3353314, at *10 (E.D. La. Oct. 19, 2009).

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[8] And the Government would be hard-pressed to contend that it did not know which manufacturers sold Ipratropium, given that its Medicare carriers specifically had to list drugs in their pricing arrays by manufacturer, and, furthermore, Medicaid Ipratropium payments were paid on a NDC-specific basis.

In any event, it was no secret to the Government that Ipratropium was a Roxane drug. Indeed, the Government, including the OIG and the Congressional Budget Office, were fully aware of that fact, since it received AMP data from Roxane for Ipratropium on a quarterly basis. (Roxane SOF ¶¶ 124-25, 128) Moreover, during its pricing investigations, the OIG not only had full access to Roxane's (and every other manufacturer's) AMPs, but in fact examined printouts of the specific AMPs for Roxane's Ipratropium for every year from 1997 to 2000. (Ex. S, 12/13/07 D. Tawes Dep. at 747-50, 754-57)

In sum, by the time VAC asserted its AWP claims regarding Ipratropium in 2002, allegations about AWP-fraud had reached a crescendo, expressly implicating Ipratropium and thus Roxane. Thus, VAC's Ipratropium claims are barred unless VAC can demonstrate that it is an original source.

3. *Allegations Of Fraud For The Additional Drugs Were Publicly Disclosed By February 2005, The Critical "Public Disclosure" Date.*

When VAC first identified the Additional Drugs in 2005, the public domain was flooded with allegations of mega-spreads and AWP-fraud. And such public disclosures were greatly amplified by state attorneys general, who filed numerous complaints alleging that Roxane inflated and marketed the spreads for the Additional Drugs. (*See, e.g.*, Roxane's MTD Memo., Ex. A, 11/17/04 Texas/VAC Compl. (naming each of the Additional Drugs); Exs. B-K, other State Complaints) VAC does not deny this. Instead, it seeks to preempt these public disclosures by arguing that they are untimely. Again, however, the filing of this action in 2000 did not stop the clock on public disclosures for allegations raised by VAC five years later. *See* discussion *supra* at § I.A. To the contrary, the State Complaints are cognizable public disclosures that predate VAC's allegations regarding the Additional Drugs, and thus trigger the jurisdictional bar

as to all claims relating to those drugs.[9] *Ortho-McNeil*, 538 F. Supp. 2d at 377, 383 (court-filed documents constitute public disclosures).

C. VAC Is Not An "Original Source" Because It Lacks Direct Knowledge.

VAC fails to show that the allegations in the Complaint are based on anything other then "second-hand information, speculation, background information, and collateral research." *United States ex rel. Hafter v. Spectrum Emergency Care, Inc*., 190 F.3d 1156, 1162-63 (10th Cir. 1999). An "original source" must have direct knowledge of the allegations—that is, knowledge "marked by the absence of an intervening agency, instrumentality, or influence." *United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 95 (D. Mass. 2001). The relator's direct knowledge must extend to each essential element of the claims asserted. *Atkinson*, 255 F. Supp. 2d at 392-93 n.48. Every item of information on which VAC relies here was obtained second-hand.

The key allegation in the Complaint is that "Roxane reported false, fraudulent and inflated drug prices." (Dkt. No. 96, Compl. at ¶ 3) VAC lacked direct knowledge of ***any*** information to support that claim. Rather, VAC's knowledge of the figures reported by Roxane came from WAC and AWP information collected, compiled, and then published by third-party pricing compendia. (VAC's Opp. at 47) Similarly, though VAC claims to have knowledge of the "true transaction prices in the marketplace" (*id*. at 23), it has no direct knowledge of the critical allegation that *Roxane* "sold" or "arranged to sell" its drugs at those prices-a deficiency that cannot be cured by reference to limited pricing information compiled and disseminated by

[9] Whether VAC played a role in the filing of any of these complaints, for example, the Texas complaint, is also irrelevant. As the court held in *Alcan*, a prior complaint can constitute a public disclosure, even if it is filed by the relator himself. *Alcan*, 197 F.3d at 1016, 1019.

third-party wholesalers and GPOs (*see id*. at 47). Accordingly, VAC "cannot qualify as an original source [because] a third party is the source of the *core information* upon which [its] qui tam complaint is based." *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58, 72 (D. Conn. 2006) (quotations omitted).

Unable to establish direct knowledge, VAC instead argues that it is an original source because of "its knowledge of the marketplace and methods by which price and spread information is communicated by and on behalf of manufacturers to . . . providers." (VAC's Opp. at 23) However, merely possessing background information which allows the relator to understand the significance of allegations that have already been publicly disclosed, *see* discussion *supra* at § I.B., does not amount to direct knowledge. *Yale*, 415 F. Supp. 2d at 72. Though VAC commends itself for having provided certain pricing information to the Government (VAC's Opp. at 2-4, 29-30), this only suggests that VAC is *a source* of information. VAC does not achieve the status of an *original source* by gathering information that is widely available, at the behest of the Government, from which deductions may be drawn. *See United States ex rel. Barth v. Ridgedale Elec., Inc.*, 44 F.3d 699, 704 (1995); *United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 473 F.3d 506, 523 (3d Cir. 2007).

Moreover, none of the information to which VAC points provides any insight regarding allegations of specific strategies by Roxane to manipulate, control, and market the spread. (Dkt. No. 96, Compl. at ¶¶ 61-65, 67) Indirect knowledge regarding Roxane's pricing does not confer original source status for VAC's WAC or AWP-inflation claims, much less for VAC's "marketing the spread" claims. While VAC presents evidence of its direct knowledge of efforts by *other, non-parties* to market the spread (VAC's Opp., Ex. Q), VAC presents no such evidence for Roxane. As a factual matter, and as a legal matter, VAC cannot rely on materials produced

by Roxane in separate litigation (VAC's Opp., Exs. J, K) to demonstrate direct knowledge of its "marketing the spread" allegations. *United States ex rel. Kreindler & Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993); *United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160-61 (3d Cir. 1991). That VAC never purchased a Roxane drug (other than Ipratropium) and never submitted a single claim for reimbursement for any Roxane product further highlights that VAC is not an "inside whistleblower," but a disinterested outsider undeserving of relator status. *O'Keeffe*, 131 F. Supp. 2d at 93, *citing Barth*, 44 F.3d at 703.

II. THE GOVERNMENT'S COMPLAINT CANNOT RELATE BACK TO VAC'S PRE-INTERVENTION COMPLAINTS BECAUSE EACH OF THOSE PLEADINGS WAS JURISDICTIONALLY DEFECTIVE.

The Government relies on *Rockwell* for the proposition that its Complaint can relate back to VAC's prior complaints, each of which was jurisdictionally defective. (U.S.' Opp. at 2-4) However, "[p]rior cases have precedential value only when there has been a deliberative consideration of the issue at hand." *Bannon*, 406 F. Supp. 2d at 927. The Supreme Court in *Rockwell* did not contemplate that the Government's complaint could relate back at all, let alone to a complaint that lacked jurisdictional basis. Moreover, *Rockwell* suggests that the relator there may have asserted a jurisdictional claim, but then pled that claim away when it adopted the Government's complaint in intervention. *Rockwell*, 549 U.S. at 474 n.6. By contrast, VAC's claims here were jurisdictionally defective from the very inception of this action. Thus, the purported "*[s]ub-silentio* or assumptive resolution [in *Rockwell*] is not enough" to warrant relation back, given the different facts here. *Bannon*, 406 F. Supp. 2d at 927. Indeed, if *Rockwell* stands for any proposition germane to this issue, it is that the intervention of the Government cannot retroactively revive or cure the defects that have tainted VAC's claims from

the outset. *See Rockwell*, 549 at 476-77; *United States ex rel. Cosens v. Yale-New Haven Hosp.*, 233 F. Supp. 2d 319, 326 (D. Conn. 2002).

The Government's reliance on *Connectu LLC v. Zuckerberg*, 522 F.3d 82 (1st Cir. 2008), is similarly misplaced. In *Connectu*, the original plaintiff itself cured the jurisdictional defect, well within the limitations period, by asserting a new claim under federal question, rather than diversity jurisdiction. Here, by contrast, there could never be any basis for jurisdiction over any of VAC's claims. And the only means by which jurisdiction could ever attach was through the intervention of the Government, and subsequent dismissal of VAC. In this respect, the facts here are more aptly analogized to cases holding that the intervention of a new party in a non-jurisdictional action creates a separate action. *See Fuller v. Volk*, 351 F.2d 323, 328-29 (3d Cir. 1965); *United States Steel Corp. v. EPA*, 614 F.2d 843, 845 (3d Cir. 1979). Because jurisdiction here is contingent on the intervention of one plaintiff that can properly invoke jurisdiction (*i.e.*, the Government) and the dismissal of another that cannot (*i.e.*, VAC), the Government's claims constitute a separate action, which cannot relate back to the original pleading. This conclusion is consistent with *Rockwell*, which acknowledges the fundamental change that occurs in the nature of a *qui tam* action when a relator is dismissed from an intervened case for lack of jurisdiction. At that point, but no sooner, the action is converted from one that is "brought" by a supposed original source to one that is "brought" by the Government. *Rockwell*, 549 U.S. at 1411-12.

A. The New FERA Relation-Back Provision Is Inapposite.

The recently enacted Fraud Enforcement and Recovery Act ("FERA") provision cited by the Government is not applicable because it does not contemplate relation back to a complaint filed by a putative relator that could never satisfy the jurisdictional prerequisites of § 3730(e)(4). FERA, Pub. L. No. 111-21, §4(f)(2), 123 Stat. 1621 (2009). Moreover, the new FERA relation-back provision applies only to "cases pending on the date of enactment," a criteria not met here.

Cases interpreting the meaning of the word "pending" in the FCA's first-to-file provision are instructive on this point. *See* 31 U.S.C. § 3730(b)(5) (providing that "[w]hen a person brings an action under [the FCA], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action"). As courts have held, an action is not "pending" such that it would bar another related action, unless the person who filed the action meets all of the jurisdictional requirements of § 3730(e)(4). *United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 323 (D. Mass. 2009) *citing United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 516 (6th Cir. 2009) ("Indeed, if the first complaint is either jurisdictionally precluded [under] 3730(e), or legally incapable of serving as a complaint . . . then it does not properly qualify as a 'pending action' brought under the FCA."); *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 823-24 (9th Cir. 2005). Similarly, given that VAC's involvement in this case continues to spoil the Court's jurisdiction, this case is not "pending" within the meaning of the FERA relation-back provision.

Finally, Section 3730(e)(4) speaks not only to the court's power, but to the "substantive rights of the parties," including Roxane. *Rockwell*, 549 U.S. at 468. Allowing the Government's claims to relate back would retroactively create jurisdiction, where none existed in the first place. Consequently, it would impermissibly expose defendants to liability for claims that are expressly time-barred under the FCA's six-year statute of limitations. Therefore, retroactive application of the FERA relation-back provision is prohibited because it would cause "retroactive effects" that alter the parties' rights under the FCA. *See United States v. Aguillon*, 628 F. Supp. 2d 542, 550 (D. Del. 2009) (holding that retroactive application of another FERA provision, § 4(f)(1), would cause impermissible "retroactive effects"). Furthermore, retroactivity would also alter the manner of punishment under the FCA, by enlarging the limitations period *post hoc*, in violation

of the Ex Post Facto Clause of the United States Constitution. *United States ex rel. Sanders v. Allison Engine Co., Inc.*, 1:95-cv-970, 1:99-cv-923, 2009 WL 3626773, *5-10 (S.D. Oh. Oct. 27, 2009) (holding that, because the FCA is punitive in nature, retroactive application of § 4(f)(1) violates the Ex Post Facto Clause).

CONCLUSION

For all the foregoing reasons, and for the reasons set forth in Roxane's Motion to Dismiss and in Section VII of Roxane's Motion for Summary Judgment, the Court lacks jurisdiction over VAC's claims against Roxane and should dismiss VAC's claims with prejudice. Moreover, because none of VAC's jurisdictionally defective complaints provided an adequate placeholder for relation-back purposes, the Government's claims are time-barred to the extent they accrued prior to January 18, 2001.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on November 23, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale
John W. Reale